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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Igor Rukhman

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

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DELIVERY MODE

10/02/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/802,627	Applicant(s) RUKHMAN ET AL.	
	Examiner SUSANNAH CHUNG	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/29/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8,9,12-14 and 81-894 is/are pending in the application.
- 4a) Of the above claim(s) 1,3-6,8,9,12-14,81,82 and 84-94 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 83 and 97-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/1/09</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 1, 3-6, 8-9, 12-14, 81-94 and 97-101 are pending in the instant application. Claims 2, 7, 10-11, 15-80 and 95-96 are canceled. New claims 97-101 are presented and will be examined with the elected subject matter.

RCE

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/29/2009 has been entered.

Response

Claims 83, 95 and 96 were previously rejected under 35 USC 103 as obvious over U.S. Pat. No. 5,399,578 ('578 Patent). Claims 95 and 96 are canceled. The rejection of claim 83 is maintained. Applicants arguments have been carefully considered, but do not present any new evidence regarding the patentability of this claim. Therefore, claim 83 is rejected for the same reasons as previously stated in office actions dated 6/14/05, 3/8/06, 11/6/06, 7/20/07, 11/7/08, and 3/6/09.

New claims 97-101 will now be considered. New claims 97 and 99-101 are directed to an amorphous form of Valsartan that is substantially free of crystalline forms of valsartan.

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Claim 98 is directed to a purely amorphous form having the XRPD pattern as depicted in figure 2

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 97-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims are indefinite because the metes and bounds of the claim cannot be ascertained. Claim 97 states that it is “Valsartan purely amorphous” then it states that it is “substantially free of crystalline forms of Valsartan.” It is unclear how a purely amorphous compound can have any crystalline forms in it. Claim 98 appears to be directed to purely amorphous Valsartan because Figure 2 is drawn to an x-ray diffraction pattern of a purely amorphous form. In addition it is unclear whether amorphous and crystalline forms are being claimed because the x-ray diffraction pattern of Figure 1 contains crystalline peaks. Since the metes and bounds of the claim are not clear, the claims are rejected as indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 97-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buhlmayer et al., U.S. Pat. Num. 5,399,578 (3/21/95) in view of Marti, U.S. P.G. Pub. Num. 2003/0171414A1 (9/11/03) now U.S. Pat. Num. 6,869,970.

Applicants instant elected invention teaches amorphous forms of Valsartan. Claim 97 is directed to an amorphous form of valsartan having some crystalline forms of Valsartan in it having an x-ray diffraction peak of Figure 1. Claim 98 is drawn to a purely amorphous form having an x-ray diffraction peak of Figure 2, but claim 98 is dependent on claim 97, which contains some crystalline forms mixed with the amorphous form.

Determination of the scope and content of the prior art (MPEP § 2141.01)

Buhlmayer teaches amorphous Valsartan mixed with crystalline forms.

Marti teaches crystalline forms of Valsartan with specific x-ray diffraction patterns.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art of Buhlmayer and the instant claims is that Buhlmayer is silent as to the x-ray diffraction patterns.

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The difference between the prior art of Marti and the instant claims is that Marti does not disclose the x-ray diffraction pattern of amorphous forms, but crystalline forms only.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

One skilled in the art would have found the claimed amorphous form mixed with crystalline forms prima facie obvious because the instantly claimed compound and the compounds in Buhlmayer and Marti are the same, i.e. Valsartan. A prima facie case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities. “An obviousness rejection based on similarity in chemical structure and function entails the motivation of one skilled in the art to make a claimed compound, in the expectation that compounds similar in structure will have similar properties.” In re Payne, 606 F.2d 303, 313, 203 USPQ 245, 254 (CCPA 1979). MPEP 2144.09.

Applicants argue that there was no suggestion in the art for valsartan with the instant x-ray diffraction patterns. It would be obvious to one of ordinary skill in the art that the instant x-ray diffraction pattern of Figure 1 contains crystalline forms. The prior art of Buhlmayer and Marti both teach that amorphous forms of Valsartan exist. Marti further states that both the crystalline and the amorphous salts and salt hydrates according to the invention have a high degree of dissociation in water and thus substantially improved water solubility. These properties are of advantage, since on the one hand the dissolving process is quicker and on the other hand a smaller amount of water is required for such solutions. Furthermore, the higher water solubility can, under

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certain conditions, also lead to increased biological availability of the salts or salt hydrates in the case of solid dosage forms. Improved properties are beneficial especially to the patients. See Marti Column 2, approximately lines 48-58.

The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological use). Valsartan is an orally active specific angiotensin II antagonist acting on the AT1 receptor subtype.

Therefore, the instant claims, which discloses an amorphous form of valsartan with x-ray diffraction patterns containing crystalline forms is not allowable over the prior art, which teaches amorphous valsartan and x-ray diffraction peaks for crystalline forms.

Conclusion

Claims 83, 97-100 and 101 are rejected.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Susannah Chung/
Examiner, Art Unit 1626